PB90-259896

Cadium: Position Document 4. Intent to Cancel Registrations of Pesticide Products Containing Cadmium: Denial of Applications for Registration of Pesticide Products Containing Cadmium; Conclusion of Special Review

(U.S.) Environmental Protection Agency, Washington, DC

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This Position Document addresses the risks and benefits of pesticide products containing the subject active ingredient. The Agency has determined that the use of products containing the subject active ingredient may meet or exceed a risk criterion described in 40 CFR Part 154. Potential hazards will be examined further to determine the nature and extent of the risk, and considering the benefits of the subject active ingredient, whether such risks cause unreasonable adverse effects on the environment.

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17. Document Analysis a. Descriptors

PESTICIDES, STANDARDS, REGULATIONS, MANUFACTURING, CHEMISTRY, TOXICOLOGY, RESIDUES, ECOLOGY, PATH OF POLLUTANTS

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ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

[OPP-30000/20D]

CADMIUM; INTENT TO CANCEL REGISTRATIONS OF PESTICIDE PRODUCTS CONTAINING CADMIUM; DENIAL OF APPLICATIONS FOR REGISTRATION OF PESTICIDE PRODUCTS CONTAINING CADMIUM; CONCLUSION OF SPECIAL REVIEW

AGENCY: Environmental Protection Agency (EPA)

ACTION: Notice of Final Determination and Intent to Cancel.

SUMMARY: On October 26, 1977, EPA initiated a Special Review of all pesticide products that contain cadmium compounds (salts of chloride, sebacate, succinate, carbonate and anilino cadmium dilactate) as active ingredients and that are registered for use on turf of golf courses and home lawns. On September 10, 1986, EPA issued a Preliminary Determination (PD 2/3) proposing to cancel registrations and deny applications for all uses of cadmium products on turf sites. The proposed cancellation action was based on the Agency's determination that the use of cadmium fungicides would result in unreasonable adverse effects to applicators of these products for these uses. A FEDERAL REGISTER Notice was published concerning these actions on October 10, 1986 (51 FR 36524).

This Notice concludes the Special Review and announces EPA's final determination to (1) cancel registrations and deny applications of all pesticide products containing any of the five cadmium compounds as active ingredients that are

registered for use on golf course fairways and home lawns, and (2) to modify the terms and conditions of registration of cadmium products for use on golf course greens and tee areas.

DATE: A request for a hearing by a registrant or applicant must be received by [INSERT DATE 30 DAYS FROM DATE OF PUBLICATION IN FEDERAL REGISTER] or 30 days from receipt by mail of this Notice, whichever is the later applicable deadline. A request for a hearing from any other adversely affected person must be received by: [INSERT DATE 30 DAYS FROM DATE OF PUBLICATION IN FEDERAL REGISTER].

ADDRESS: Requests for a hearing must be submitted to:

Hearing Clerk (A-110),
Environmental Protection Agency,
401 M St., S.W.,
Washington, DC 20460.

Other relevant addresses are found under Unit IV and Unit V.D. 1.

FOR FURTHER INFORMATION CONTACT:

By mail:

Valerie Meredith Bael
Special Review Branch,
Registration Division (TS-767C),
Office of Pesticide Programs,
Environmental Protection Agency,

401 M St. S.W.,

Washington, DC 20460.

Office location and telephone number:

Room 1006, Crystal Mall Building #2,

1921 Jefferson Davis Highway,

Arlington, Virginia 22202,

(703) 557-2314

SUPPLEMENTARY INFORMATION: This Notice is organized into six units. Unit I is the Introduction. It provides the background information concerning this regulatory action. Units II and III summarize the applicator risks and the benefits associated with the use of cadmium on golf courses and home lawns. They also contain a review and evaluation of comments received by the Agency in response to the PD 2/3. Unit IV contains the comments of the Scientific Advisory Panel, the Secretary of Agriculture, and other public comments and EPA's response to those comments. Unit V describes the Agency's final determination, the regulatory actions required by this Notice, and the procedures which will be followed in implementing the regulatory actions EPA is announcing in this Notice. Unit VI is the bibliography.

I. INTRODUCTION

A. REGULATORY HISTORY

On October 26, 1977, a FEDERAL REGISTER Notice (42 FR 56574) was published concerning the Special Review of all pesticide

products that contain as an active ingredient cadmium compounds (salts of chloride, sebacate, succinate, carbonate and anilino cadmium dilactate) and that are registered for use on turf of golf courses and home lawns. This action was based on the determination that cadmium pesticide products exceeded risk criteria relating to oncogenicity, mutagenicity, teratogenicity, and fetotoxicity.

Following review of public comments and available data, a Preliminary Determination was issued on October 10, 1986, in which the Agency determined that the risk concerns relating to oncogenicity remained and risk concerns for kidney effects were added. Risk concerns for mutagenicity, teratogenicity and fetotoxicity no longer remain. A review of the many mutagenicity tests provided conflicting results because of the many end points and protocols used. The Agency concluded that the weight of evidence from the composite of the many studies does not support the risk criteria for mutagenicity. Based on the Agency's review of animal studies, cadmium has been shown to produce developmental toxicity (embryotoxicity, fetotoxicity and teratogenicity) at high dose levels. The available data are not considered adequate to support the risk criteria for teratogenic and fetotoxic effects at exposure levels encountered by pesticide applicators.

The October 10, 1986 Notice announced (1) the Preliminary Determination proposing to cancel registrations for all

pesticide products that contain cadmium compounds as active ingredients that are used on turf of golf courses and home lawns based on oncogenic and kidney risks, and (2) the availability of the Support Document. The Support Document (Ref. 1) contains the background information which supported the Agency's actions. This information included an assessment of the hazard to applicators, the benefits of use on golf courses and home lawns, and a discussion of measures to reduce exposure to applicators. In consideration of the toxicological effects of cadmium compounds, the estimated potential risks of these effects to applicators, the lack of effective measures to mitigate these unacceptable risks, the availability of effective alternatives and an estimated minor economic impact to users, the Agency concluded that the risks of continued use of cadmium pesticide products outweighed the benefits. Therefore, the Agency proposed cancellation of all pesticidal uses of cadmium compounds.

This Notice concludes the Special Review and announces EPA's final determination to cancel registrations and deny applications of all registered uses of cadmium on golf course fairways and home lawns and to modify the terms and conditions of registration for products used on golf course greens and tee areas. The weight of evidence continues to lead the Agency to conclude that the oncogenic and kidney risks associated with the use of cadmium on golf course greens and tee areas

(with hand-held sprayers), and the kidney risks associated with the use of cadmium on golf course fairways by ground boom sprayers and on home lawns outweigh the low benefits. The use of cadmium on golf course fairways and home lawns may also pose some oncogenic concern. During development of the PD 2/3, the Agency assumed that heavy mechanical power spray equipment could not be used on greens and tee areas. Therefore, exposure estimates used in the Agency's risk assessment for greens and tee areas were based on hand-held spray equipment only. Since publication of the PD 2/3, the Agency received new information indicating that most golf course applicators use power spray equipment (i.e., mini-boom sprayers and walking boom sprayers) rather than hand-held sprayers to apply cadmium to greens and tee areas. The Agency defines a "mini-boom" sprayer as a boom that can be drawn by a small vehicle. The Agency reviewed its existing data base and determined that it lacks adequate data on this application method. In order to assess the risk of oncogenic and kidney effects from the use of this equipment, the Agency has required applicator exposure data through a FIFRA section 3 (c)(2)(B) Data Call in Notice. Deadline for submission of these data is July, 1988. The Agency will allow continued use of cadmium on golf course greens and tee areas with the following modifications in the terms and conditions of registration: (1) "Restricted Use" for retail sale to and use

ouly by certified applicators and only for those uses covered by the Certified Applicator's certification, (2) application to golf course greens and tees only, (3) application by mini-boom sprayers only, and (4) use of protective clothing during mixing, loading and application (chemical resistant gloves at all times and chemical resistant apron during mixing and loading). If exposure data on mini-boom sprayers indicate unreasonable risks to applicators, further regulatory action will be taken.

B. LEGAL BACKGROUND

In order to obtain a registration for a pesticide under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, an applicant for registration must demonstrate that the pesticide satisfies the statutory standard for registration, section 3(c)(2)(B) of FIFRA. That standard requires, among other things, that the pesticide performs its intended function without causing "unreasonable adverse effects on the environment." The term "unreasonable adverse effects on the environment" is defined under FIFRA section 2(bb) as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." This standa: requires a finding that the benefits of the use of the pesticide exceed the risks of use, when the pesticide is used in compliance with the terms and conditions of registration or

in accordance with commonly recognized practices.

The burden of proving that a pesticide satisfies the standard for registration is on the proponents of registration and continues as long as the registration remains in effect. Under FIFRA section 6, the Administrator may cancel the registration whenever it is determined that the pesticide causes unreasonable adverse effects on the environment. The Agency created the RPAR process, now known as the Special Review process, to facilitate the identification of pesticide uses which may not satisfy the statutory requirements for registration and to provide an informal procedure to gather and evaluate information about the risks and benefits of these uses.

A Special Review is initiated if a pesticide meets or exceeds the risk criteria set out in the regulations at 40 CFR 154.7. The Agency announces that a Special Review is initiated by issuing a notice for publication in the FEDERAL REGISTER. Registrants and other interested persons are invited to review the data upon which the review is based and to submit data and information to rebut the presumption by showing that the Agency's initial determination of risk was in error, or by showing that use of the pesticide is not likely to result in any significant risk to humans or the environment. In addition to submitting evidence to rebut the risk presumption, commenters may submit evidence as to whether

the economic, social, and environmental benefits of the use of the pesticide outweigh the risk of use. Unless all presumptions of risk are rebutted, the Special Review is concluded by issuance of a Notice of Intent to Cancel.

In determining whether the use of a pesticide poses risks which are greater than the benefits, the Agency considers possible changes to the terms and conditions of registration which can reduce risks, and the impacts of such modifications on the benefits of use. If the Agency determines that such changes reduce risks to the level where the benefits outweigh the risks, it may require that such changes be made in the terms and conditions of registration. Alternatively, the Agency may determine that no changes in the terms and conditions of the registration will adequately ensure that use of the pesticide will not pose any unreasonable adverse effects. If the Agency makes such a determination, it may seek cancellation and, if necessary, suspension. In either case, the Agency may issue a Notice of Intent to Cancel the registration. If the Notice requires changes in the terms and conditions of registration, cancellation may be avoided by making the specified corrections set forth in the Notice, if possible. Adversely affected persons may also request a hearing on the cancellation of a specified registration and use, and if they do so in a legally effective manner, that registration and

use will be maintained pending a decision at the close of an administrative hearing.

II. SUMMARY OF THE AGENCY'S RISK ASSESSMENT AND RESPONSE TO COMMENTS

In this unit the Agency provides a summary of the oncogenic and kidney hazards associated with the use of cadmium on golf courses and home lawns. This includes information discussed in the PD 2/3, as well as a review and discussion of comments received by the Agency after the Preliminary Determination to Cancel all cadmium registrations was issued.

A. SUMMARY OF THE APPLICATOR RISK ASSESSMENT IN THE PD 2/3

In the PD 2/3 the Agency evaluated laboratory animal and human epidemiological studies and concluded that cadmium compounds are oncogenic and can cause kidney effects.

Based upon results of the studies in which (1) rats exposed to cadmium chloride aerosol by inhalation developed lung tumors, (2) rats and mice injected with cadmium or cadmium salts developed injection site, testicular and pancreatic islet tumors, and (3) workers exposed to airborne cadmium and cadmium compounds experienced a dose-related increase in lung tumors, the Agency has classifed cadmium as a "probable" human carcinogen (Group B1 substance) according

to the Agency's Cancer Assessment Guidelines, 51 FR 33992 (September 24, 1986).

The Agency prepared a risk assessment of the oncogenic risks of persons applying cadmium fungicides to golf courses and home lawns based on inhalation exposure studies. Only inhalation exposure (rather than inhalation and dermal exposures) was considered pertinent because the toxicological data base supported the formation of lung tumors following inhalation exposure by laboratory animals and smelter workers. The oncogenic risks (via inhalation) for golf course applicators range from 10^{-4} (applying cadmium to greens and tee areas by hand-held sprayers) to 10^{-6} (applying cadmium to fairways by ground boom sprayers). The oncogenic risks for home lawn applicators is 10^{-8}. Although the oncogenic risks could be reduced by one order of magnitude by the use of half-face respirators, the Agency does not believe this equipment would be rigorously utilized by golf course applicators or home lawn applicators. Hence, a label requirement for respiratory protection is not likely to provide risk reduction in actual practice.

The Agency further concluded that the risk criteria for kidney effects has been met based on results of (1) animal studies which showed that high doses of cadmium resulted in formation of fatty bodies and degeneration of renal tubules,

and (2) human studies in which chronic inhalation exposure to cadmium was associated with renal tubular proteinurea (which is symptomatic of increasingly severe irreversible kidney damage). Friberg et al. (1974) estimated that the lowest observed effect level (LOEL) associated with humans is 5 ug/kg/d (Ref. 2). A no observable effect level (NOEL) has not been established.

In order to assess the risks of exposure to pesticidal cadmium on the human kidney, the Agency conducted a quantitative assessment of the ratio of the low effect level (LOEL) derived from the Friberg study to the estimated inhalation and dermal exposures from registered uses. These comparisons are expressed as "Effect Ratios" (ERs). Although the LOEL is a chronic dose, the Agency feels it is appropriate to use this value in its risk assessment because: (1) cadmium is a cumulative toxicant whose half-life in the body is unusually long (10-30 years in man), (2) excretion via urine and the gastrointestinal tract is extremely low, and (3) its consequent adverse health effects appear to be essentially irreversible. In order to accurately assess risks to workers having intermittant, acute exposure, the Agency used an "annualized" LOEL of 0.18 mg/kg/yr based on the human inhalation data. To estimate inhalation ERs, the annualized LOEL was divided by inhalation exposure estimates for each application scenario. To estimate dermal ERs, the LOEL was multiplied by the ratio

of absorption rates for inhalation (40 percent) to dermal (1 percent) exposure and then divided by dermal exposure estimates.

The following table presents dermal and inhalation ERs for golf course (greens and tee areas and fairways) and home lawn applicators. Also included are dermal ERs assuming proper use of protective gloves for golf course applicators. Dermal ERs with protective gloves are not given for home lawn applicators because protective gloves are not considered to be rigorously utilized by this population due to cost and inconvenience.

In calculating the ERs, the Agency made the following assumptions: (1) cadmium is applied to golf course greens and tee areas by hand-held sprayers, to golf course fairways by ground boom sprayers, and to home lawns by hose-end sprayers, (2) cadmium is applied to golf course turf and home lawns at the rate of 0.2 oz ai/1000ft^2, and (3) cadmium is typically applied to golf course turf 8-12 times per year and to home lawns 3 times per year.

Cadmium Effect Ratios for Kidney Effects

Applicator	Application Equipment	ERs	ERs with Protective Gloves
Golf Course			
• Greens and tees	Hand-held spray gun		
dermal		0.1	3
inhalation		4.3	n/a
• Fairways	Ground boom sprayers		
dermal		45	91
inhalation		418	n/a
Home Lawns	Hose-end sprayers		
dermal		81	n/a
inhalation		6666	n/a

B. NEW INFORMATION CONCERNING APPLICATION

Since publication of the PD 2/3, the Agency received information indicating that power spray equipment ("mini-boom" sprayers) are commonly used to apply cadmium to golf course greens and tee areas. During development of the PD 2/3, the Agency assumed that heavy mechanical power spray equipment could not be used on greens and tee areas. Therefore, exposure estimates for greens and tees were based on hand-held spray guns only.

In a telephone conversation with a representative of the Golf Course Superintendents Association of America the Agency was informed that the majority of golf course applicators use power spray equipment (i.e., "mini-boom") to apply cadmium to greens and tee areas (Ref. 3). Smaller golf courses are still likely to treat greens and tee areas with hand-held sprayers.

Results of a published study submitted to the Agency by a major registrant indicate that dermal exposure to the limbs and torso during mini-boom application is lower than during hand-held spraying (Ref. 4). In the study several fungicides (benomyl, cycloheximide, cadmium succinate, thiophanate-ethyl) and insecticides (carbaryl and trichlorfon) were applied to golf course turf by various application methods: (1) hand-held spray guns, (2) a boom carried on a small vehicle ("mini-boom"), and (3) a boom sprayer pushed by hand. Cadmium succinate applied without protective clothing by a hand-held sprayer at a rate of 0.5 oz/1000ft^2 yielded the highest dermal exposures levels recorded of all the other pesticides. Dermal pads placed outside the clothing of applicators applying benomyl by mini-boom sprayers showed levels of residue below detection limits (10 ug/100cm^2). Similar results were observed with the application of thiophanate-ethyl and trichlorfon (detection limit not given) by hand pushed boom; however, when thiophanate and carbaryl were applied with the same

equipment, detectable residues were found. An explanation of these different results was not provided. The major deficiency in the study was that hand exposure was not measured, which can account for a significant percentage of total dermal exposure. Although the study was found to be inadequate for regulatory purposes, it does provide qualitative data regarding exposure during application by mini-boom spraying.

C. CONCLUSIONS CONCERNING APPLICATOR RISKS

Based on the hazard assessment described in the Support Document and on the new information, the Agency concludes that the weight of evidence demonstrates that (1) unreasonable oncogenic and kidney risks are associated with the use of cadmium on golf course greens and tee areas (with hand held sprayers) and, (2) unreasonable kidney risks are associated with use of cadmium on golf course fairways and home lawns. Due to the absence of adequate exposure data, the Agency is currently unable to calculate oncogenic and kidney risks to applicators applying cadmium to greens and tee areas by power spray ("mini-boom") equipment. The use of cadmium on golf course fairways and home lawns may also pose some oncogenic concern. Nevertheless, based on application rates, application pressure levels, and the small acreage of greens and tees, the Agency believes that oncogenic and kidney risks may be lower with mini-boom sprayers than with hand-held sprayers. In order to consider appropriate regulatory action for this

application method, the Agency has required applicator exposure data through a Section 3(c)(2)(B) Data Call in Notice. Deadline for submission of these data is July, 1988. Once these data are received and reviewed, oncogenic and kidney risks will be reassessed for golf course greens and tee uses.

III. SUMMARY OF THE AGENCY'S BENEFITS ANALYSIS AND RESPONSE TO COMMENTS

In this unit the Agency provides a summary of the benefits associated with the use of cadmium on golf courses and home lawns. This includes information discussed in the PD 2/3, as well as a review and discussion of comments received by the Agency after the PD 2/3 proposing to cancel all cadmium registrations was issued.

A. SUMMARY OF THE BENEFITS ANALYSIS IN THE PD 2/3

Cadmium is a low volume pesticide used primarily in the mid-western states of Michigan, Ohio, Indiana, Illinois and Minnesota for control of copper spot, red thread and grey snow mold turf diseases on golf courses and home lawns. The benefits of cadmium were assessed in the PD 2/3 in terms of the economic impact which would result if cadmium were cancelled and users chose to use other registered pesticides as alternatives. Eleven alternatives were evaluated as to their known toxicological risks. The Agency has initiated or completed

Special Reviews and/or Registration Standards on a number of the alternatives. Triadimefon is one alternative that has shown no adverse oncogenic, mutagenic or reproductive effects. Although it does show a positive teratogenic effect, the Margins-of-Safety (NOEL/estimated exposures) are larger than 100.

Although several fungicides are available to control the aforementioned turf diseases, only cadmium and triadimefon are registered to control all three diseases. Because triadimefon is the only fungicide which is registered to control each of the turf diseases controlled by cadmium, it was assumed that all golf course acreage historically treated with cadmium would be treated with triadimefon if cadmium were unavailable. Based on this assumption, the economic impact of the cancellation of cadmium fungicides for use on golf courses is estimated to be $240,000 annually. The increased cost of substituting triadimefon would be approximately $500 annually for each of the affected golf courses. Because cadmium fungicides are not sufficiently effective against diseases which are of primary concern to the average homeowner, very little cadmium is used by home lawn applicators. Therefore, practically no economic impact would result from cancellation of cadmium use on home lawns.

B. NEW INFORMATION CONCERNING THE BENEFITS

In response to the PD 2/3, the Agency received two written comments (as attachments to a comment received from a registrant) regarding the benefits of continuing registrations of cadmium pesticides and one personal communication. The first commenter was a turfgrass pathologist from the University of Rhode Island who commented that although cadmium compounds are no longer widely used, they are of value in disease resistant programs (Attachment A To Ref. 5). The Agency agrees with the commenter that having a variety of available fungicides is significant for turfgrass resistance suppression although it is difficult to measure this impact in economic terms. However, the Agency does not believe that the cancellation of cadmium for the golf course fairway use will create a resistance problem because of the many alternatives available.

The second commenter, a representative of the Golf Course Superintendent's Association of America (GCSAA), reported that in a survey of 300 golf course superintendents cadmium usage on golf course turf was very low. None of the superintendents in the survey reported using the product more than twice a year. Nevertheless, the majority of the superintendents polled stressed the value of having cadmium available to their pest managers to control disease resistant pathogens. GCSAA recommended to the Agency that cadmium be a restricted

use chemical and sold as a liquid or dry flowable to decrease applicator exposure (Attachment B. To Ref. 5). The Agency is, in fact, restricting the use of cadmium on golf course greens and tee areas (Unit V.B.), rather than cancelling this use.

The third comment was a personal communication between a representative of the GCSAA and the Agency. In the conversation, the Agency was informed that cadmium is used mostly on golf course greens and tee areas; very little, if any, is used on fairways (Ref. 3). The commenter stated that the greens and tee areas account for approximately 2 acres while fairways account for over 40 acres of the golf course acreage. He further noted that use on greens and tee areas is a high priority activity for golf course superintendents. This information supports the Agency's conclusion that the benefits of use of cadmium on golf course fairways is very low, and that cancellation of this use is not expected to have any significant economic impact.

C. CONCLUSIONS CONCERNING THE BENEFITS

The impact of cancellation estimated in the Support Document did not change as a result of the new information. Based on the new information, the Agency concludes that although the majority of golf course superintendents polled agree that cadmium is a valuable component in turfgrass resistance programs, the use of cadmium may be lower than

originally estimated in the PD 2/3. Therefore, the Agency's estimate of the cost impact of cancellation may have been overstated.

IV. COMMENTS OF THE SCIENTIFIC ADVISORY PANEL, THE SECRETARY OF AGRICULTURE, AND THE PUBLIC

The Agency transmitted the Support Document to the United States Department of Agriculture (USDA) and the Scientific Advisory Panel (SAP) for review and requested comment. The Agency also submitted additional information (Ref. 6) to the SAP. Unit IV A and B contain the SAP and USDA comments and the Agency's response. The Agency also received public comments in response to the public comment period for the FEDERAL REGISTER Notice. These comments along with the Agency's response are summarized in Unit IV.C.

Copies of all comments, minutes of meetings with and correspondence among various interested parties are contained in a docket maintained for this Special Review, as provided in EPA's Special Review regulations under 40 CFR Part 154, published in the FEDERAL REGISTER of November 27, 1985 (50 FR 49003).

The docket is available for public inspection from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays in: Rm. 236, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

A. COMMENTS OF THE SCIENTIFIC ADVISORY PANEL

EPA presented its proposed decision to the SAP in a

public meeting held on November 19, 1986. On November 25, 1986 the Panel responded to EPA. The Panel's comments are reproduced in their entirety.

FEDERAL INSECTICIDE, FUNGICIDE
AND RODENTICIDE ACT (FIFRA)
SCIENTIFIC ADVISORY PANEL

A Set of Scientific Issues Being
Considered by the Agency in Connection
with the Special Review of Cadmium Fungicides

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP) has completed review of the data base supporting the Environmental Protection Agency's (EPA) decision to cancel registrations and to deny applications for pesticide products containing cadmium compounds for use on turf. The review was conducted in an open meeting held in Arlington, Virginia, on November 18, 1986. All panel members, except Dr. Harold L. Bergman, Dr. John J. Lech and Dr. Thomas W. Clarkson, were present for the review.

Although Dr. Clarkson was not present at the Panel meeting on November 19, 1986, he was present at the meeting on November 20, 1986.

Dr. Clarkson provided his comments to the Panel on November 20, 1986, and agreed with the Panel's recommendations.

Public notice of the meeting was published in the FEDERAL REGISTER on Friday, October 24, 1986.

Oral statements were received from staff of the Environmental Protection Agency and from Mr. Martin W. McGinn and Dr. Paul Sartoretto of W.A. Cleary Chemical Corporation.

In consideration of all matters brought out during the meeting and careful review of all documents presented by the Agency, the Panel unanimously submits the following report.

REPORT OF PANEL RECOMMENDATIONS: CADMIUM

The Agency requested the Panel to focus its attention upon a set of scientific issues relating to the Special Review of Cadmium Fungicides. There follows a list of the issues and the Panel's response to each issue:

ISSUE:

Friberg, et. al., (1974), concluded that the critical concentration of cadmium in the renal cortex of humans, associated with renal dysfunction, is 200 ug/g. Since cadmium is

a cumulative poison (acute exposure will add to the body burden) and the half-life for elimination of cadmium is very long, the Agency requests any comments that the Panel may wish to make regarding the use of the Friberg data to assess the risks to workers having intermittant, acute exposure to cadmium fungicides.

Panel Response:

The Panel believes that the Friberg, et. al., (1974) report contains reliable and dependable scientific data that can be used to assess the risks to workers having intermittant, acute exposure to cadmium fungicides. The Panel further believes that the small quantity of cadmium that is used as a fungicide would not constitute a threat to man or the environment. Thus, the restricted use of cadmium that was suggested to the Panel becomes a risk-benefit decision outside the purview of this committee.

FOR THE CHAIRMAN

Certified as an accurate report of the Findings:

Stephen L. Johnson
Executive Secretary

FIFRA Scientific Advisory Panel

Date: November 25, 1986

The SAP's comments support the scientific basis for the Agency's conclusions concerning kidney effects from cadmium application to golf courses and home lawns. The SAP commented that the small amount of pesticidal cadmium would not constitute a threat to man or the environment. The Agency agrees, that compared to occupational exposure (approximately 1.5 million workers), pesticidal exposure to cadmium is minimal. Nevertheless, the oncogenic and kidney risks to applicators applying cadmium pesticides to golf course turf and the kidney risks to home lawns applicators are unacceptable in light of the low benefits and inadequacy of reasonable protective measures for the use pattern of this pesticide.

B. USDA's COMMENTS

The USDA's comments on the Special Review and the proposed cancellation are printed in full below:

Mr. Douglas D. Campt, Director
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, DC 20460

Dear Mr. Campt:

This is the Department of Agriculture's response to EPA's preliminary decision to cancel the registrations and deny applications for all products containing cadmium registered for use on turf.

We do not have any objection to your proceeding with your proposal as indicated.

Sincerely,

Charles L. Smith, Coordinator,
Pesticides and Pesticide Assessment

C. PUBLIC COMMENTS RECEIVED IN RESPONSE TO THE SPECIAL REVIEW

The Agency received 3 comments relating to the preliminary determination to cancel all registrations of cadmium for use on golf courses and home lawns. Two comments received were from registrants and one was from Public Citizen Health Research Group.

One registrant proposed the following label changes which it claimed would reduce pesticidal exposure to applicators: (1) Restricted Use Pesticide for use only by Certified Golf Course Superintendents, (2) use on golf course greens, tees and aprons only, (3) application by power spraying equipment only, and (4) requirement for the use of protective clothing (rubber gloves, long sleeve shirts, pants, apron, and body-covering clothing) (Ref. 5). Along with these proposed changes, the registrant included letters from a turfgrass pathologist from the University of Rhode Island and the Golf Course Superintendents Association of America. These comments are discussed in Unit III.B. The same registrant later submitted a formal written request to the Agency for the aforementioned label changes (Ref. 7). These proposed changes are in fact included in this Notice.

Another registrant stated that cadmium products are applied at a lower application rate per year (2.56 lb/A/yr) than the estimate which was stated in the Draft Notice of Intent to Cancel and therefore yield lower risks to applicators (Ref. 8). Contrary to the contention of this commenter, the estimate of 30 lb/A/yr stated in Unit IV of the Draft Notice of Intent to Cancel was based on the maximum allowable label rate. This estimate was not used for the Agency's risk assessment purposes. Oncogenic and kidney risk estimates were based on annual application rates of 2.4 to 4.8 oz ai/1000ft^2 (golf course greens and tees), 0.9 oz ai/1000ft^2 (golf course fairways) and 0.6 oz ai/1000ft^2 (home lawns).

Public Citizen supported the Agency's proposal to cancel all cadmium registrations based on oncogenic and kidney risks to applicators. They also contended that the Agency's risk assessments are likely to understate the risks for cancer and kidney damage since they fail to take into account additional exposure from skin absorption and ingestion (Ref. 9). The Agency believes that the regulatory measures set forth in this Notice will provide adequate protection to applicators. The Agency's risk assessments for oncogenicity and kidney effects were based on applicator inhalation and dermal exposure to pesticidal cadmium. However, the Agency also considered additional potential exposures from ambient sources (including food and water) and concluded that for certain sensitive

individuals any additional cadmium accumulation over a long period of time may be sufficient to cause adverse health effects. As noted above, even without these additional factors, the risks calculated for oncogenicity and kidney damage were unreasonable in light of the low benefits of use for golf course fairways and home lawn uses, and for the golf course greens and tee area uses without the protective measures required by this Notice.

V. INITIATION OF REGULATORY ACTION

This unit has several sections. The first section summarizes EPA's reasons for concluding that products containing the active ingredient cadmium be cancelled for all registered uses on golf course fairways and home lawns. The second section describes the Agency's final determination and the regulatory actions required by this Notice. The third section establishes provisions concerning the sale, distribution, and use of existing stocks of cancelled products. The last section outlines procedures which will be followed in implementing the regulatory actions set forth in this Notice.

A. AGENCY'S CONCLUSIONS

Based on the Agency's analysis in the Support Document and the information reviewed after the Notice of Special Review was issued, the Agency has concluded that the risk of oncogenic and kidney effects to applicators outweighs the benefits of use of cadmium on golf course greens and tee areas (with hand-

held sprayers), and that the risk of kidney effects outweighs the benefits of use for fairways and home lawns. The use of cadmium on golf course fairways and home lawns may also pose some oncogenic concern. Oncogenic and kidney effects associated with applying cadmium to golf course greens and tee areas (with mini-boom sprayers) cannot be assessed due to the lack of adequate exposure data. Nevertheless, as discussed in Unit II.C., the Agency believes that oncogenic and kidney risks on greens and tee areas may be lower with mini-boom sprayers than with hand-held sprayers.

In evaluating the hazards, the Agency considered cadmium's chronic toxicity, estimated exposures to applicators, and application practices. In evaluating the benefits, the Agency considered the user cost impact of cancellation and the efficacy of cadmium and its major alternatives.

The Agency also considered requiring protective clothing (i.e., elbow length gloves and half-face respirators) and prohibiting use of hand-held sprayers as alternatives to cancellation and concluded the following:

1. For golf course greens and tee areas (hand-held sprayers), protective clothing (i.e., elbow length gloves) would not sufficiently reduce the risks of kidney effects. Dermal ERs would increase from 0.1 to 3. Requiring half-face respirators could reduce oncogenic risks from 10^{-4} to 10^{-5} but the Agency believes that this equipment would not be

rigorously utilized for the golf course use. Prohibiting the use of hand-held spray equipment is expected to reduce both oncogenic and kidney effects to reasonable levels, based on currently available data.

2. For golf course fairways, elbow length gloves would not sufficiently reduce kidney risks. Dermal ERs would increase from 45 to 91.

3. For home lawns, kidney risks would not be sufficiently reduced by requiring protective gloves, as the Agency believes this equipment would not be rigorously utilized for the home lawn use pattern. Prohibiting the use of hand-held sprayers on home lawns would be tantamount to cancellation due to a lack of suitable alternative application equipment.

The weight of evidence leads the Agency to conclude that the risks associated with application of cadmium to home lawns, golf course greens and tee areas (by hand-held sprayers) and golf course fairways, outweigh the minor benefits and that cancellation of these uses is the only appropriate action. The Agency intends to cancel all current uses of cadmium on home lawns and golf course fairways. The risks associated with application of cadmium to golf course greens and tee areas (by mini-boom sprayers) cannot be quantitatively assessed due to the lack of adequate exposure data. Therefore, the Agency is requiring applicator exposure data on this application method. The Agency intends to continue registrations

of cadmium on golf course greens and tee areas with label modifications as outlined in Unit V.C. of this document.

B. FINAL DETERMINATION AND REQUIREMENTS FOR COMPLYING WITH THIS NOTICE

1. The Agency has determined to cancel the registrations and deny applications for registration for all products containing cadmium compounds (salts of chloride, sebacate, succinate, carbonate, and anilino cadmium dilactate) and registered for use on golf course fairways.

2. The Agency has determined to cancel the registrations containing cadmium compounds (salts of chloride, sebacate, succinate, carbonate, and anilino cadmium dilactate) and registered for use on home lawns.

3. The Agency has determined that modifications to the terms and conditions of registration are necessary for all products containing cadmium compounds (salts of chloride, sebacate, succinate, carbonate, and anilino cadmium dilactate) and registered for use on golf course greens and tees. In order to avoid cancellation, registrants of cadmium products labeled for use on golf course greens and tees must make the modifications specified below to the labeling of their products within 30 days of publication of this Notice in the FEDERAL REGISTER or within 30 days of receipt of this Notice, whichever is later, as set forth in Unit V.D. of this Notice:

a. RESTRICTED USE pesticide for retail sale to and use only by certified applicators or persons under the direct supervision of a certified applicator and only for those uses covered by the Certified Applicator's certification.

b. Cadmium has been shown to produce kidney toxicity in humans and tumors in laboratory animals.

c. This product is only to be applied by power boom spraying equipment to golf course greens and tee areas only. Do not apply through portable, manned or hand-held pump sprayers.

d. Wear chemical resistant gloves, long sleeve shirts, and long legged pants. In addition, wear a chemical resistant apron during mixing and loading.

e. Wash gloves with soap and water before removing. Launder all clothing worn during use before reusing and launder separately from household articles.

For a cadmium product which is currently labeled for multiple uses subject to this Notice, the registrant must amend the label, within the time specified by Unit V.D. of this Notice, to delete the cancelled uses and modify the other uses in accordance with the requirements of this Notice in order to avoid cancellation of the product.

C. EXISTING STOCKS

The following paragraphs describe the conditions under which registrants and others may sell and distribute existing stocks of cancelled cadmium products. Existing stocks may not be sold and distributed except as provided below:

1. No manufacturer may release for shipment after January 31, 1988, any cadmium product subject to this Notice unless the product bears an amended label or has supplemental labeling affixed which complies with Unit V.B.

2. No cadmium product subject to thi Notice may be distributed or sold by a retailer or other person after April 30, 1988, unless the product bears an amended label or has supplemental labeling affixed which complies with Unit V.B.

D. PROCEDURAL MATTERS

This Notice announces EPA's determination to cancel the registrations of products that contain cadmium and that are used on golf course fairways and home lawns. This Unit also explains how registrants may apply to amend their registrations for cadmium products registered for use on golf course greens and tee areas to comply with the terms and conditions discussed in Units V.B. and C. above.

Under sections 6(b) and 3(c)(6) of FIFRA, applicants, registrants, and certain other adversely affected persons are also entitled to respond to this Notice by requesting a hearing on the actions that EPA is initiating. Unless a

hearing is properly requested with regard to a particular registration or application, this action will become final by operation of law.

This section of the Notice explains how such persons may request a hearing on EPA's final cancellation and denial Notice (and the consequences of requesting a hearing and failing to request a hearing in accordance with those procedures).

1. Procedure for Amending the Terms and Conditions of Registration to Avoid Cancellation or Denial of Application. Registrants affected by the cancellation actions set forth in this Notice may avoid cancellation by filing for an application for an amended registration which contains the label modifications detailed in Unit V.B. of this Notice. This application must be filed within 30 days of receipt of this Notice or within 30 days from the publication of this Notice, whichever occurs later. Applicants for a registration subject to this Notice must file an amended application registration within the applicable 30-day period to avoid denial of their pending application.

Applications must be submitted to:

Lois Rossi,
Product Manager 21,
Registration Division (TS-767C),
Office of Pesticide Programs,
Environmental Protection Agency,
401 M St., S.W.,
Washington, DC 20460,
(703-557-1900).

2. Procedures for Requesting a Hearing. To contest the cancellation action set forth in this Notice, Federal registrants or applicants may request a hearing within 30 days of receipt of his Notice, or within 30 days from publication of this Notice, whichever occurs later. Any other person adversely affected by the action described in this Notice may request a hearing within 30 days of publication of this Notice in the FEDERAL REGISTER.

A registrant or other adversely affected party who requests a hearing must file the request in accordance with the procedures established by FIFRA and EPA's Rules of Practice Governing Hearings under 40 CFR Part 164. These procedures require, among other things, that all requests must identify the specific pesticide product(s) for which a hearing is requested, and that all requests must be received by the Hearing Clerk within the applicable 30-day period. Failure to comply with these requirements will result in a denial of

the request for a hearing. Requests for a hearing should also be accompanied by objections that are specific for each use of each pesticide product(s) for which a hearing is requested.

Requests for a hearing must be submitted to:

Hearing Clerk (A-101),
Environmental Protection Agency,
401 M St., S.W.,
Washington, DC 20460.

a. Consequences of filing a timely and effective hearing request. If a hearing on the action initiated by this Notice is requested in a timely and effective manner, the hearing will be governed by EPA's Rules of Practice for hearings under FIFRA section 6 (40 CFR Part 164), as modified below. The hearing will be limited to the specific uses and specific product registrations for which the hearing is requested.

In the event of a hearing, the specific use or uses of the specific registered product which is the subject of the hearing will not be cancelled except pursuant to an order of the Administrator at the conclusion of the hearing.

b. Consequences of failure to file in a timely and effective manner. If a hearing concerning the registration of a specific pesticide product subject to this Notice is not requested by the end of the applicable 30-day period, registra-

tion of that product will be cancelled, unless the registrant files a request for an amended registration within the statutory period provided herein (See Unit V.D.1).

If the registration of a product covered by this Notice is cancelled by operation of law, the sale and distribution of existing stocks is governed by the provisions of Unit V.C. of this Notice.

3. Separation of functions. EPA's Rules of Practice forbid anyone who may take part in deciding this case, at any stage of the proceeding, from discussing the merits of the proceeding ex parte with any party or with any person who has been connected with the preparation or presentation of the proceeding as an advocate or in any investigative or expert capacity, or with any of their representatives (40 CFR 164.7).

Accordingly, the following EPA offices, and the staffs thereof, are designated as the judicial staff to perform the judicial function of EPA in any administrative hearing on this Notice of Intent to Cancel: the Office of the Administrative Law Judge, the Office of the Judicial Officer, the Administrator, the Deputy Administrator, and the members of the staff in the immediate office of the Administrator and Deputy Administrator. None of the persons designated as the judicial staff may have any ex parte communication with the trial staff or any other interested person not employed by EPA on the merits of any of the issues involved in this

proceeding, without fully complying with the applicable regulations.

VII. REFERENCES

The references in this FEDERAL REGISTER Notice are as follows:

(1) U. S. Environmental Protection Agency. "Cadmium Technical Support Document," U.S. Environmental Protection Agency, 1986, Public Docket No. D-5838A.

(2) Friberg, L., Piscator, M., Nordberg, G.F., Kjellstrom, T. "Cadmium In The Environment", 2nd. ed., CRC Press, Inc., Boca Raton, Florida, 1974, Public Docket No. D-05783, Att. 23.

(3) Golf Course Superintendents Association of America. Personal communication (telephone) between Jerry Faubel, Golf Course Superintendents Association of America and Valerie Bael, EPA, January 30, 1987, Public Docket No. D-7644.

(4) Daniel, W.H., Freeborg, R.P., and Knopinski, V.J. "An On-Course Look At Pesticide Exposure," Golf Course Management, March, 1984, pp. 71-85, Public Docket No. D-7645.

(5) W. A. Cleary Chemical Corporation. Response of W. A. Cleary Chemical Corporation to the Special Review and Proposed Cancellation of cadmium, W.A. Cleary Chemical Corporation, November 24, 1986, Public Docket No. D-6607, submitted to USEPA December 2, 1986, with attachments:

A. University of Rhode Island. Response to the Special Review and Proposed Cancellation of Cadmium. A letter to Mr. Martin McGinn of the W.A. Cleary Chemical Corporation, University of Rhode Island, Kingston, RI.

B. Golf Course Superintendents Association of America. Response to the Special Review and Proposed Cancellation of Cadmium. A letter to Mr. Martin McGinn of the W. A. Cleary Chemical Corporation.

(6) U.S. Environmental Protection Agency. Materials submitted to the Scientific Advisory Panel in consideration of the Special Review of Cadmium, USEPA, November 7, 1986, Public Docket No. D-7754.

(7) W.A. Cleary Chemical Corporation. Proposed label change, W.A. Cleary Chemical Corporation, January 12, 1987, Public Docket No. D-7753, submitted to USEPA January 16, 1987.

(8) Seacoast Laboratories. Response of Seacoast Laboratories to the Special Review and Proposed Cancellation of Cadmium, Seacoast Laboratories, November 3, 1986, Public Docket No. D-6034, submitted to USEPA November 14, 1986.

(9) Public Citizen. Response of Public Citizen to the Special Review and Proposed Cancellation of Cadmium, Public Docket No. D-6115A, submitted to USEPA November 21, 1986.

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All references with Public Docket numbers are available for inspection in Rm. 236, Crystal Mall Building #2, 1921 Jefferson Davis Highway, Arlington, VA., from 9 a.m. to 4 p.m., Monday through Friday excluding legal holidays.

Dated: 4 Aug 83

John A. Moore
Assistant Administrator
for Pesticides and
Toxic Substances

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL
Mary F. Travers